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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/519,728 | 03/03/2000 | Bruce D. Weintraub | UOFMD.002C1 | 6702 |

7590

03/26/2003

Supervisor Patent Prosecution Services
PIPER RUDNICK
1200 NINETEENTH STREET NW
WASHINGTON, DC 20036-2412

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| EXAMINER |
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SPECTOR, LORRAINE

| ART UNIT | PAPER NUMBER |
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1647

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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16

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/26/02

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 27-31, 39, 62, 67-74 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 27-31, 39, 62, 67-74 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Part III: Detailed Office Action

Notice: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Lorraine Spector in Group Art Unit **1647**.

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Claims 27-31, 39, 62 and 67-74 are pending and under consideration.

Double Patenting:

10 Claims 27-31, 39, 62 and 67-68 remain, and newly introduced claims 69-74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-43 and 47-57 of U.S. Patent Number 6,361,922 in view of U.S. Patent Number 5,585,345 for reasons of record in paper number 12 at pages 3-4. Applicants arguments in paper number 14 filed 12/26/02 have been fully considered but are not deemed persuasive. Applicants argue that the claims of the '922 patent are "not commensurate in scope with all the possible combinations of
15 single-site substitutions contemplated by Applicants' claims." This argument has been fully considered but is not deemed persuasive because The claims of the '922 patent include species within applicant's ranges- that is all that is required, as the species anticipates the range. Applicants further arguments with respect to the Boise reference are addressed below with respect to the rejection under 35 U.S.C. § 103(a).

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Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims

under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27, 31 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Szkudlinski, Nature Biotech. in view of Boise, U.S. Patent Number 5,585,345, for reasons of record in the previous Office Action, paper number 12, at pages 4-5. Applicants arguments in paper number 14 filed 12/26/02 have been fully considered but are not deemed persuasive.

Applicants argue that Szkudlinski does not teach C-terminal extensions or other modifications other than amino acid substitutions, and that Boise does not teach amino acid substitutions as claimed herein. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants arguments pertaining to substitutions at positions 58-68 are moot, as those claims are not subject to this rejection. However, it is noted that Szkudlinski et al. specifically teach that substitution at position 67 (R67K) had *no effect* on biological activity of TSH.

Applicants argument that Boise does not teach modification of TSH is not persuasive; see claim 4 of Boise. Applicants argument at page 6 of the response that Boise suggests the extension of *in vivo* activity of the proteins, and does not address *in vitro* activity has been fully considered but is not deemed persuasive. It is not necessary that Boise's motivation be identical to applicants'.

Applicants argument at page 7 that the higher *in vitro* activity is unexpected and would not have been predicted based upon the prior art has been fully considered but is not deemed persuasive, as it is not clear that the level of increase is sufficient to rise to the level of an unexpected result; the data on Figure 5 are not sufficient to support the assertion at page 42 that the addition of the CTP

increased *in vitro* activity by an additional 3-4 fold. Further, because said result applies only to a single species, α 4K; such unexpected results, by their very natures, cannot be extrapolated to non-exemplified embodiments. Finally, where the unexpected properties of a claimed invention are not shown to have a significance equal to or greater than the expected properties, the evidence of unexpected properties may not be sufficient to rebut the evidence of obviousness (*In re Nolan*, 553 F.2d 1261, 193 USPQ 641 (CCPA 1977)). In this case, the uses taught by the specification for the claimed invention are *in vivo* uses. Boise teaches that *in vivo* half-life would be expected to be increased. Accordingly, a teaching of a minor or even moderate increase of *in vitro* activity would not rebut the finding of obviousness, as it is the *in vivo* performance of the protein that is of significance.

Advisory Information:

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

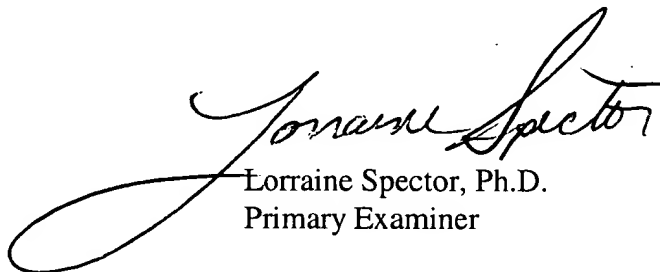
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Serial Number 09/519728
Art Unit 1647

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.



Lorraine Spector, Ph.D.
Primary Examiner

LMS
09/519728.s1
3/26/03